REMARKS

Applicant requests reconsideration of the application in view of the foregoing amendments and the discussion that follows. The status of the claims as of this response is as follows: Claims 1-47 are pending and are subject to restriction. Claims 1, 2, 5-7, 11, 12, 15, 16 and 21-27 have been amended herein and Claims 28-47 have been canceled without prejudice to Applicant's right to file divisional applications to the separately patentable subject matter thereof.

The Amendments

Certain paragraphs of the specification were amended to correct typographical errors in the original text. Support therefor is in the specification as originally filed since the corrections are evident from the original text. The paragraph on page 18, line 30, to page 19, line 9, was amended to correct the definition of r and s. Support therefor is in the specification, for example, original Claims 23 and 24.

Claim 1 was amended to recite that the second linking group is linked to the first linking group. Support therefor is in the specification, for example, page 11, line 4.

Claim 2 was amended to recite "further comprising." Support therefor is in the specification, for example, original Claim 2.

Claim 5 was amended to delete "a functional group" from the definition of Y and to correctly show the relationship between Z and t in the next to last paragraph of the claim.

Claim 6 was amended to refer to "the same corresponding positions in A and M." Support therefor is in the specification, for example, page 10, lines 16-31.

Claim 7 was amended to recite "enzyme label." Support therefor is in the specification, for example, page 6, lines 9 and 16.

Claim 11 was amended to correctly show the relationship between Z_1 and t' in the next to last paragraph of the claim.

Claim 12 was amended in a manner similar to that for Claim 7.

Claim 15 was amended to delete "a bond" from the definition of Z' and to correctly show the relationship between Z' and t" in the second from last paragraph of the claim.

Claim 16 was amended in a manner similar to that for Claim 7.

Claim 21 was amended to delete "a bond" from the definition of Z" and to correctly show the relationship between Z" and t"' in the second from last paragraph of the claim.

Claim 21 was also amended to recite "enzyme label." Claim 21 was also amended to correct the definition of r and s. Support therefor is in the specification, for example, original Claims 23 and 24.

Claim 22 was amended in a manner similar to that for Claim 7.

Claims 23-25 were amended to recite R_1' and R_2'. Support therefor is in the specification, for example, original Claims 23-25.

Claims 26 and 27 were amended in a manner similar to that for Claim 7.

Restriction Requirement

Restriction was required under 35 U.S.C. §121 to one of the following inventions:

Group I – Claims 1-27, drawn to a compound comprising amphetamine and methamphetamine, classified in class 564, subclass 336.

Group II – Claims 28-47, drawn to a method and kit for determining amphetamine and methamphetamine in a sample, classified in class 435, subclass 7.1.

During a telephone conversation with the Examiner on May 23, 2005, a provisional election was made with traverse to prosecute the invention of Group I, Claims 1-27. Applicant hereby affirms this election. It should be noted that the Office Action indicates that the provisional election was made without traverse. The undersigned's notes reflect that the election was made with traverse.

In the Restriction Requirement in the present Office Action, the Examiner stated that the above inventions are independent and distinct, each from the other, for the reasons set forth in the Office Action. Accordingly, the Examiner has determined that the inventions of the various groups are separately patentable over one other. According to M.P.E.P. 802.01 the term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (emphasis in original). Consequently, the restriction requirement necessarily involved the Examiner's determination at least implicitly that the inventions of the various groups are separately patentable over one other. If this were not the case, then the restriction requirement would not be appropriate.

Furthermore, it follows from the above that art (if such art exists) indicating that the invention of one of the groups is known or would have been obvious would not extend to a holding that the invention of the other group are known or would have been obvious. For example, art that might anticipate or render obvious a compound as set forth in Claim 1 would not render known or obvious a reagent system comprising a compound of Claim 1 as set forth in Claim 28, or a method as set forth in Claim 29, 33 or 38, or a kit as set forth in Claim 43 or vice versa. Again, if this were not the case, then the restriction requirement with respect to those claims would not be proper.

Rejection under 35 U.S.C. 112, second paragraph

Claims 1-27 were rejected under the second paragraph of the above code section as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action asserts that it is unclear in Claims 1, 5 and 11 what the chemical nature and scope of the term "linking group". The Office Action further asserts that the point of attachment of the "second linking group" to the "first linking group" is also unclear.

Applicant respectfully traverses this ground of rejection. The specification contains a detailed discussion of the linking groups and the point of attachment of the second linking group to the first linking group. For example, the specification (page 9, lines 9-17) states that the bivalent haptens comprise a linking group between the two moieties so that both the amphetamine moiety and methamphetamine moiety are extended substantially equally in space and, in some embodiments, are symmetrically disposed, allowing each of the hapten moieties equal opportunity to interact with a corresponding antibody. The linking group typically has a functional group in the middle of its scaffold where the functional group is available for further elaboration of the molecule such as by attaching a linking group for linking to a label. The functional group permits the incorporation of a tether or second linking group, which has a functionality ready for attachment to an attachable moiety, for example, a label such as, e.g., an enzyme.

In the last paragraph on page 10, Applicant discloses that in some embodiments, the amphetamine moiety and the methamphetamine moiety are linked to the first linking group in a substantially symmetrical manner. In other words the two moieties are linked to the first linking group from the same corresponding positions in the

respective moieties. In this way the moieties are disposed in the bivalent conjugate such that they are essentially mirror images of one another except for the presence of a methyl group in the methamphetamine moiety, instead of hydrogen, on the amine group. In some embodiments, the moieties are linked from the respective phenyl groups and, in some embodiments, from the 3-positions on the respective phenyl groups. However, the moieties may be linked from other positions of the respective molecules and on the phenyl groups as long as the moieties are specifically recognized by their respective antibodies to the extent necessary to obtain a sensitive and accurate assay for amphetamine and/or methamphetamine.

The nature of the linking groups and the distances between the amphetamine and methamphetamine moieties is elaborated further beginning on page 11, line 4, to page 13, line 18. The phrase "approximately the same" as well as other phrases are discussed in this section of the specification.

In view of the detailed disclosure in Applicant's specification, one skilled in the art would have a full understanding of the subject matter that Applicant regards as the invention with regard to the nature of the linking groups and the linking arrangement between the amphetamine and the methamphetamine moieties.

The Office Action contends that Claim 1 is vague and indefinite as the exact configuration of the "compound" is unclear. The Office Action asserts that the claim recites the term "the distance" in line 3 and is not clear whether "the distance" is in terms of number of molecules or in terms of nanometers. The aforementioned paragraphs from Applicant's disclosure at page 11, line 4, to page 13, line 18, provides one skilled in the art with a clear understanding of the phrase "the distance." The Office Action further argures that it is also unclear what is meant by the term "depends" in line 2 of Claim 1. Applicant submits that the amendment to Claim 1 obviates this ground of rejection.

The Office Action contends that the term "stereospecific" in line 2 of Claim 4 is not clear as to its meaning. The term "stereospecific" is defined in Applicant's specification, for example, page 11, lines 1-3. Applicant indicates that the term means that the amphetamine moiety and the methamphetamine moiety are the respective stereoisomers that are physiologically active.

With respect to claim 5, the Office Action asserts that it is not clear how the different moieties are attached to each other (i.e., point of attachment of A to L, M to L, Y to L and Y

to Z). In Claim 5, A and M are linked to each other through a linking group. Y is a bond or a linking group that is bonded to L at a point equidistant between A and M. The nature of the linking groups and points of attachments, as well as a discussion of the distances, is found in Applicant's specification, for example, page 9, lines 7-17, the last paragraph on page 10, and page 11, line 4, to page 13, line 18.

The Office Action further contends that Claim 5 recites the phrase "Y is a bond, a functional group" alnd that it is not clear how Y can be a functionl group. Applicant believes that the amendment to Claim 5 is this regard renders this ground of rejection moot.

The Office Action also asserts that it is not clear what is encompassed by the terms "poly(amino)" and "non-poly(amino)" label moiety in Claim 5. These terms are discussed in detail in the specification, for example, at the paragraph bridging pages 14-15.

Applicant submits that the amendment to Claim 6 obviates the rejection of this claim as set forth in the Office Action.

With respect to Claims 7, 12, 16 and 22, the Office Action asserts that it is not clear what is encompassed by the term enzyme. Applicant has amended these claims to recite "enzyme label" and this phrase is discussed in detail in Applicant's specification as mentioned above.

Claims 11, 15, 21 and 25 were rejected for recitation of the term "protecting group". The Office Action contends that it is not clear what is encompassed by this term because "protecting group" is a general term which includes numerous groups for protection of functional groups -OH, -NH, -SH, -COOH and -CO. Therefore, concludes the Office Action, these claims are vague and indefinite for not clearly defining the protecting group.

First, the term "protecting group" is used in the claims for a substituent on an -N- functionality. Second, the specification discusses in detail what is meant by the term. See, for example, page 10, lines 6-15. Finally, the term is well-known to those skilled in the art.

With respect to claims 15 and 21, the Office Action contends that it is not clear to what Z is it connected to when the variable "Z" is "a bond". Applicant believes that the amendment to the above claims obviates this ground of rejection.

The Office Action contends that in Claims 22-25 at line 1, the variables R_1 and R_2 need to be corrected in order to avoid insufficient antecedent basis because the claims

depend from claim 21 which recites RI' and R2'. Applicant has made the above correction in Claims 22-25.

Applicant submits that the amendment to Claim 21, from which Claims 23-24 depend, avoids the rejection of those claims with regard to the definition of "r" and "s."

With respect to claims 5, 11, 15, 21 and 26, the Office Action asserts that it is unclear how the multiple structures are linked to one another. As discussed above, the nature of the linking groups and points of attachments as well as a discussion of the distances is found in Applicant's specification, for example, page 9, lines 7-17, the last paragraph on page 10, and page 11, line 4, to page 13, line 18.

Applicant submits that the amendments to Claims 5, 11, 15 and 21 obviate the rejection of those claims regarding the definitions of "t" and "Z" and variations thereof such as t' and Z', etc. Applicant further submits that Claim 26 as originally filed provides sufficient definition for the corresponding terms used therein.

Rejection under 35 U.S.C. 112, first paragraph

Claims 1-27 were rejected under 35 U.S.C. 112, first paragraph, because, asserts the Office Action, the specification, while being enabling for specific linking groups and configurations as set forth the in working examples, is, however, not enabling for the entire scope encompassed. The specification, continues the Office Action, provides guidance for use of acetamido and alkylene group as linking groups, but there in no enablement in the specification for use of all other linking groups such as phosphodiester or peptide. The Office Action contends that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant disagrees with the above rejection. The legal standard for challenging a specification on enablement is set forth in *Gould v. Mossinghoff*, 229 USPQ 1, 14 (D.D.C. 1985), aff'd in part, vacated in part, and remanded sub nom., *Gould v. Quigg*, 822 F.2d 1074, 3 USPQ2d 1302 (Fed. Cir. 1987): "In examining a patent application, the P.T.O. is required to assume that the specification complies with the enablement provision of Section 112 unless it has 'acceptable evidence or reasoning' to suggest otherwise....The P.T.O. thus must provide reasons supported by the record as a whole why the specification is not enabling....Then and only then does the burden shift to the applicant to

show that one of ordinary skill in the art could have practiced the claimed invention without undue experimentation." The burden is on the Examiner to establish that the specification lacks the requisite enabling disclosure and then only when there is reason to doubt the truth of statements contained in the specification. *In re Marzocchi*, 439 F.2d 220, 169 USPQ (CCPA 1971). An enabling disclosure is all that is required. *Ex parte Erlich*, 3 USPQ2d 1011, 1014 (P.T.O. Bd. Pat. App. & Int'f 1987). In applying the enablement requirement, the invention that must be enabled is that defined by the claims of the application. *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 R. Supp. 1278, 6 USPQ2d 1065 (D. Del. 1987), aff'd, 865 F.2d 1247, 9 USPQ2d 1461 (Fed. Cir. 1989). The specification must teach those of skill in the art how to make and use the invention as broadly as it is claimed. *In re Goodman*, 11 F.3d 1046, 1050, 29 USPQ2d 2010 (Fed. Cir. 1993).

Claims 1-27 are fully enabled by the present Specification. The claims are directed to compounds comprising both an amphetamine and a methamphetamine moiety. The nature and breadth of the invention claimed in Claim 1 is a conjugate of an amphetamine moiety and a methamphetamine moiety linked together by a linking group and having, for example, a functional group of a second linking group further attached to this linking group by, for example, a bond or a second linking group where point of linkage of the second linking group to the first linking group is approximately the same. As mentioned in the present specification (page 8), the present invention permits effective screening of samples for the presence of an amphetamine or a methamphetamine using a smaller number of reagents than that employed in prior art methods. The specification (page 9) indicates that, in the present invention, a three-component reagent system that includes a single label conjugate and two antibodies is employed. Embodiments of the present invention utilize a bivalent hapten reagent that incorporates both amphetamine and methamphetamine moieties in a single chemical entity. This particular synthetic entity can then be conjugated to, for example, a label to produce a label conjugate comprising the amphetamine and methamphetamine moieties. The bivalent haptens comprise a linking group between the two moieties so that both the amphetamine moiety and methamphetamine moiety are extended substantially equally in space and, in some embodiments, are symmetrically disposed, allowing each of the hapten moieties equal

opportunity to interact with a corresponding antibody. The linking group typically has a functional group in the middle of its scaffold where the functional group is available for further elaboration of the molecule such as by attaching a linking group for linking to a label.

The linking groups may be any linking groups so long as the amphetamine and methamphetamine moieties are linked together in a manner such that the point of attachment of a label moiety is substantially equidistant between the amphetamine moiety and the methamphetamine. One skilled in the art can easily carry out the present invention without undue experimentation. As has been held, an enabling patent specification is one that teaches those skilled in the art how to make and use the full scope of the invention without undue experimentation. The specification need provide nothing more than objective enablement, however. Moreover, the enabling teaching may be provided through broad terminology or illustrative examples. *In re Wright*, 999 F.2d 1557, 1561, 27 U.S.P.Q. 2d 1510 (Fed. Cir. 1993). The present specification meets the aforementioned criteria.

Claims 2-27 are fully enabled by the present Specification for the reasons set forth above with respect to Claim 1. Applicant submits that the subject matter of Claims 2-27 is described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The question is whether the disclosure is sufficient to enable those skilled in the art to practice the claimed invention; hence, the specification need not disclose what is well known in the art. Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 481, 489 (Fed. Cir. 1984) Applicant submits that the present claims and specification meet the above standard. The skilled artisan is well aware of linking groups, and the guidance in the specification as to the spacing between the moieties is sufficient to permit the skilled artisan to select linking groups to achieve the benefits of the claimed invention.

As mentioned above, it is well recognized that the specification need provide nothing more than objective enablement. The present specification indeed provides such enablement. However, the present specification also provides illustrative examples. A specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of Section 112 unless there is reason to doubt the

objective truth of the statements contained therein which must be relied on for enabling support. *Fiers v. Revel v. Sugano*, 984 F.2d 1164, 25 USPQ 2d 1601, 1607 (Fed. Cir. 1993); *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (C.C.P.A. 1971). The present disclosure coupled with the knowledge of the skilled artisan clearly enables the practice of the inventions as claimed in Claims 1-27.

Conclusion

Applicant has demonstrated that Claims 1-27 satisfy the requirements of 35 U.S.C. 112. Allowance of the above-identified patent application, it is submitted, is in order.

Respectfully submitted,

Theodore J. Leitereg
Attorney for Applicant
Reg. No. 28,319

Theodore J. Leitereg
31420 Pennant Ct.
Temecula CA 92591
(602) 369-1751